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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,192	08/02/2001	David C. Turner	VTN-548	6090

7590 02/24/2005

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EXAMINER

PURVIS, SUE A

ART UNIT PAPER NUMBER

1734

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,192

Applicant(s)

TURNER ET AL.

Examiner

Sue A. Purvis

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,27-30 and 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,14-16,18,21,23-25,31,32,36,38-40,52-87 is/are rejected.
- 7) ☒ Claim(s) 4,11,17,19,20,22,26,33-35,37 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC §103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 1-3, 6, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of Suzuki (US Patent No. 6,486,262 B1).

On pages 1 and 2 of the specification, the applicant admits that the use of hydrogels to form contact lenses is well known. That it is desirable to increase the surface wettability of hydrogel articles by coating the articles with a hydrophilic coating. Numerous hydrophilic coatings and methods for their application are known. It is known to use solution- or solvent-based coatings to coat lenses. Application of a coating onto a mold into which a lens material is dispensed has been disclosed. This method has been successfully demonstrated with non-silicone hydrogel materials. It is noted by the examiner that the claim uses alternative language and the mixture creating the lens does not have to contain silicone. The admitted prior art does not discuss a "dwell time."¹²

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a dwell time in the admitted prior art of less than about 5

¹ As defined in the applicant's specification, "dwell time" is the elapsed time from which the monomer mixture is dispensed into the mold until curing commences. (Applicant's disclosure, page 16, lines 24-26.)

² During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner

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minutes, because to leave monomer mixture in the mold for more than 5 minutes would slow the process down.

Regarding claims 2 and 15, the article in the admitted prior art is a contact lens.

Regarding claims 6 and 18, a dwell time of less than 45 second is within the purview of the artisan because it quickens the process, but not delaying the curing step.

Regarding the coating having to be "a high molecular weight coating composition."³ While the admitted does not specifically use the terminology "high molecular weight" as a feature of the coating composition, the process of the admitted prior art makes the applicant's claim obvious.⁴

3. Claims 5, 7, 8, 14, 15, 23, 31, 32, 55-63, 67-75, and 79-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art as applied to claim 1 above, and further in view of LeBoeuf et al. (US Patent No. 6,632,887 B2).

The admitted prior art does not disclose the molecular weight of the coating material. LeBoeuf discloses that it is important for the hydrophilic polymer to have high molecular weight. (Col. 3, lines 15-26.) It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a high molecular weight composition within the applicant's claimed range, because LeBoeuf discloses the importance of the coating having a high molecular weight.

Regarding claim 7, a dwell time of less than 45 second is within the purview of the artisan because it quickens the process, but not delaying the curing step.

Regarding claims 8 and 23, LeBoeuf disclose that including solvents in the coating composition is well known and its within the purview of the artisan to include a low BP solvent and a high BP solvent.

reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).

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Regarding claims 55-63, 67-75, and 79-87, ethanol and ethyl lactate are well known solvents and it is within the purview of the artisan to use them and use the appropriate ratio of the solvents.

4. Claims 9, 10, 21, 24, 25, 36, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of LeBoeuf as applied to claims 1, 8, 15, and 23 above, and further in view of Bae et al. (US Patent No. 5,667,735).

The admitted prior art in view of Suzuki and LeBoeuf does not discuss the manner in which the material is coated onto the mold. Bae discloses spin coating is a well known means of coating a mold when making contact lenses. (Col. 1, lines 16-20.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use coating in the admitted prior art in view of Suzuki and LeBoeuf, because Bae discloses that spin coating is a well known form of coating a mold.

Regarding claims 10 and 25, the amount of coating composition is based on the size of the mold and the amount claimed is within the purview of one having ordinary skill in the art.

Regarding claims 39 and 40, the manner in which the material is coated onto the mold is not disclosed. Bae discloses spin coating is a well known means of coating a mold when making contact lenses. (Col. 1, lines 16-20.) It would have been obvious to one having ordinary skill in the art at the time the invention was made to use spin coating, because Bae discloses that spin coating is a well known form of coating a mold.

Regarding claim 40, the amount of coating composition is based on the size of the mold and the amount claimed is within the purview of one having ordinary skill in the art.

³ As defined in applicant's specification, "high molecular weight is meant an average molecular weight ("Mw") sufficiently high so as to avoid dissolution of coating into the monomer mixture used." (Applicant's disclosure, page 3, lines 12-14.)

⁴ The purpose of the coating is to remain on the surface of the contact lens, not to mix with the hydrogel.

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5. Claims 64-66 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art in view of LeBoeuf et al as applied to claims 14 and 31 above, further in view of Enns (US Patent No. 5,779,943).

Enns discloses that viscosity of the coating composition can be manipulated. (Col. 5, lines 19-26.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to manipulate the viscosity of the coating composition based on the needs of the artisan as disclosed in Enns. Thus it is within the purview of the artisan to have the coating composition be the viscosities as claimed in the instant application.

Response to Arguments

6. Applicant's arguments filed 22 Nov. 2004 have been fully considered but they are not persuasive.

7. Regarding applicant's remarks with respect to the §103 rejection, the applicant has misstated some of the rejections by leaving out the admitted prior art which was used in those rejections, thus applicant's arguments are flawed because they fail to include the admitted prior art which was used as the primary reference in the §103 rejections. The proper rejections made were as follows:

- a. Claim 1-3, 6, 14-16, and 18 over ***the admitted prior art*** in view of Suzuki (US Patent No. 6,486,262 B1),
- b. Claims 5, 7, 8, 14, 15, 23, 31, 32, 55-63, 67-75, and 79-87 over ***the admitted prior art*** in view of Suzuki as applied to claim 1 above, and further in view of LeBoeuf et al. (US Patent No. 6,632,887 B2).

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c. Claims 9, 10, 24, and 25 over ***the admitted prior art*** in view of Suzuki and LeBoeuf as applied to claims 1, 8, 15, and 23 above, and further in view of Bae et al. (US Patent No. 5,667,735).

8. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Allowable Subject Matter

9. Claims 4, 11, 17, 19, 20, 22, 26, 33-35, 37, and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is an examiner's statement of reasons for allowance:

a. For claims 11, 22, 26, 37, and 41, the reasons for allowance are set forth in the office action dated 21 July 2004.

b. Regarding claims 4, 17, 19, 20, and 33-35, the independent claims use alternative language in step (b), not requiring that the monomer mixture contain silicone. These claims require the mixture to include a silicone & the examiner was unable to find a teaching where a silicone hydrogel monomer mixture is used to form a contact lens by coating the mold as defined by the independent claims

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue A. Purvis whose telephone number is (571) 272-1236. The examiner can normally be reached on Monday through Friday 9am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher A. Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sue A. Purvis
Primary Examiner
Art Unit 1734

SP
February 21, 2005